UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,681	02/20/2007	Sergei Anatolievich Lukyanov	U 015745-9	6233

140 7590 09/25/2008

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
09/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,681	LUKYANOV ET AL.	
	Examiner	Art Unit	
	WU-CHENG Winston SHEN	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The claim amendments filed on 02/20/2007 have been entered. Claims 31, 6-10, 14, 17, 18, 21, 22, and 24 are amended. Claims 25 and 26 are newly added. Claims 1-26 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-6, 12, 13, 17, and 18, drawn to **(i)** an isolated nucleic acid molecule, which encodes a fluorescent or chromo-protein, selected from the group consisting of: (a) A nucleic acid which encodes a protein comprising the amino acid sequence as shown in SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 20 or 22; (b) a nucleic acid comprising a nucleotide sequence as shown in SEQ ID NOs: 1, 3, 5, 7,9, 11, 13, 15, 17, 19 or 21; (c) a nucleic acid that hybridizes under stringent conditions to the nucleic acid of (a) or (b) above; (d) a nucleic acid that encodes a protein that has at least about 75% sequence identity to the amino acid sequence of (a) above; (e) a nucleic acid that has at least about 70% sequence identity to the

nucleotide sequence of (b) above; (f) a nucleic acid which encodes a protein having at least one amino acid substitution, deletion or insertion in the amino acid sequence as shown in SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 or 22; (g) a derivative or mimetic of the nucleic acid of (a), (b), (c), (d), (e) or (f) above; (h) a mutant of the nucleic acid of (a), Co), (c), (d), or (e) above; (i) a nucleic acid which differs from the nucleic acid of (b), (c), (d), (e), (f), (g) or (h) above due to the degeneracy of genetic code; and (j) a fragment of the nucleic acid of (a) or (b) above encoding a peptide of at least 15 amino acid residues in length; **(ii)** a vector comprising the nucleic acid molecule according to claim 1, and **(iii)** an expression cassette comprising (a) the nucleic acid molecule according to claim 1; and (b) regulatory elements for the expression of said nucleic acid molecule in a desired host cell.

II. Claims 7 and 8, drawn to a cell comprising the nucleic acid molecule according to claim 1, a stable cell line comprising the nucleic acid molecule according to claim 1.

III. Claim 9, drawn to a transgenic plant comprising the nucleic acid molecule according to claim 1.

IV. Claim 10, drawn to a transgenic animal comprising the nucleic acid molecule according to claim 1.

V. Claim 11, drawn to a method for producing a fluorescent or chromo-protein, said method comprising (a) providing a nucleic acid molecule according to claim 1 operably linked to suitable expression regulatory elements (b) expressing the

fluorescent or chromo-protein from said nucleic acid molecule, and (c) isolating the protein substantially free of other proteins.

VI. Claim 14, drawn to an isolated fluorescent or chromo-protein selected from the group consisting of: (a) a protein comprising the amino acid sequence as shown in SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 or 22; b) a protein encoded by the nucleic acid molecule comprising a nucleotide sequence as shown in SEQ II3 NOs: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19 or 21; (c) a protein that has at least about 75% sequence identity to-the amino acid sequence of (a) or (b) above; (d) a mutant of the protein of (a), (b) or (c) above; (e) a protein having at least one amino acid substitution, deletion or insertion in the amino acid sequence as shown in SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 or 22; (f) a derivative of the protein of (a), (b), (c), (d) or (e) above; (g) a fragment of the protein of (a), (b), (c), (d), (e) or (f) above comprising of at least 15 amino acid residues in length; and (h) a protein having a sequence that is substantially the same as, or identical to the amino acid sequence of at least 100 residues in length of (a) or (b) above.

VII. Claim 15, drawn to a fusion protein comprising the protein according to claim 14.

VIII. Claim 16, drawn to an antibody specifically binding to the protein according to claim 14.

IX. Claim 19, drawn to a method for making a biological molecule, comprising coupling said biological molecule to the protein according to claim 14.

X. Claim 20, drawn to a method for labeling a cell comprising production of the protein according to claim 14 in the cell.

XI. Claim 21, drawn to a method for labeling a cell organelle comprising production of the protein according to claim 14 fused to a suitable subcellular localization signal in the cell.

XII. Claim 22, drawn to a method for analyzing a biological molecule, cell or cell organelle comprising detection of fluorescence signal from the protein according to claim 14.

XIII. Claim 23, drawn to a method for analyzing a biological molecule, cell or cell organelle comprising expression of the nucleic acid molecule according to claim 1 in a cell.

XIV. Claim 24, drawn to a method of detecting a biological molecule comprising detection of fluorescence signal from the protein according to claim 14.

XV. Claim 25, drawn to a method for analyzing a biological molecule, cell or cell organelle comprising detection of fluorescence signal from the protein according to claim 15.

XVI. Claim 26, drawn to a method of detecting a biological molecule comprising detection of fluorescence signal from the protein according to claim 15.

Each Group of Groups I-XVI is subjected to the <u>further restrictions</u> to (i) a specific SEQ ID NO of amino acid sequence selected from the group consisting of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, 16, 20, and 22, (ii) a specific SEQ ID NO of nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19 and 21. It is required that the election of a specific SEQ ID NO of amino acid sequence and the election of a specific SEQ ID

NO of nucleic acid sequence to be consistent. In other words, it is required that the elected specific SEQ ID NO of amino acid sequence is encoded by elected specific SEQ ID NO of nucleic acid sequence. This is not a requirement for election of species.

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

Although the MPEP deems that up to ten nucleotide sequences may be searched without restriction, the Commissioner has stated that, "The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371." See Examination of Patent Applications Containing Nucleotide Sequences 1316 OG 122 (March 27, 2007). **For this reason, restriction to ONE SEQUENCE is being applied to all applications at this time.**

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed polynucleotide sequences, the Markush group shall be regarded as being of similar nature when: (A) all alternatives have a common property or activity and

(B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives or (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant sequences are considered to be each separate inventions for the following reasons:

The sequences do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. Each nucleic acid molecule encodes a distinct fluorescent or chemo-protein, which is distinct in structure and function, and requires different processes of excitation and emission for detection. The sequences do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between the nucleic acid sequences of the instant application is lacking and each nucleic acid sequence claimed is considered to constitute a special technical feature.

3. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Applicant's claims encompass multiple inventions, multiple products (nucleic acid, protein, antibody, transgenic plant, transgenic animal) and multiple methods (methods of making and methods of using the products), and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. Furthermore, there is no common technical feature in all groups.

MPEP 1893.03(d) Unity of Invention Rejoinder

4. MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Wu-Cheng Winston Shen, Ph. D.
Patent Examiner
Art Unit 1632

/Thaian N. Ton/
Primary Examiner, Art Unit 1632